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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,945	11/13/2001	Juan Mantelle	041457-0633	6420

22428 7590 05/05/2009
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ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/986,945
Filing Date: November 13, 2001
Appellant(s): MANTELLE ET AL.

Courtenay C. Brinckerhoff
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/08/2008 appealing from the Office action mailed 7/10/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 93/00058	Miranda	01/1993
EP 0524776	Pfister et al.	01-1993
US 5,284660	Lee et al.	02-1994
US 5230898	Hortsman	07-1993
US 6316022	Mantelle et al.	10/2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a) Claim 1 and dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "below processing temperatures" the phrase renders the claim unclear because neither the processing temperature nor the active agent is known.

b) Claims 1, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "equal to or greater than the normal boiling points of the at least one low molecular weight drug". The meaning is vague since the drug is not known; there is no way to compare its boiling point to the prior art.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1-6, 10-21 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda Jesus et al. WO 9300058 (Miranda).

Miranda teaches transdermal drug delivery system and more particularly, to a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition. The composition comprises a blend of polymers, and a therapeutically effective amount of a drug or more, which amount may reach between 5-40% by weight; this percentage is within the percentage recited in claim 6 (page 2). In a preferred embodiment of the improved pressure-sensitive adhesive, the first polymeric adhesive material is a polyacrylate and the second adhesive material is a polysiloxane (page 6). The shear resistant of the acrylic polymer in a preferred embodiment of the invention, the multiple polymer adhesive system comprises a blend of an acrylic shear-resistant pressure-sensitive adhesive and a silicone pressure-sensitive adhesive (page 5). Miranda discloses that the transdermal drug delivery device may include a backing material and a release liner as is known in the art (page 3). The drug comprised in the transdermal system may be nicotine (page 7), and the pressure-sensitive adhesive composition of the type, which is suitable as a matrix for controlled release of a bioactive agent (page 5). Miranda also discloses a free base, free acid drug (claim 34) and teaches that polyacrylate is preferably present in the pressure-sensitive adhesive composition in an amount ranging from about 2-96% by weight and the polysiloxane is present in an amount ranging from about 98-4%, and the composition according to Miranda comprises fillers, and excipients (page 6). The same steps of instant claim 17 are recited in (example 1) of Miranda and the nitroglycerin was added as a solution in toluene mixed together with the polyacrylate.

The resulting composition had the ingredient concentrations on a "dry" basis, that is, after removal of volatile process solvents. Note that the molecular weight of nicotine is 162.23 g/mol which reads on the instant claims that require the molecular weight of the active agent is lower that 300 Daltons.

Because the same compounds have same properties, the recitation of "pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit" is an inherent property to the same compounds of the preparation disclosed by Miranda.

b. Claims 1-5, 7, 8, 10, 12, 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al EP0524776.

Pfister teaches a silicone pressure sensitive adhesive composition, which is compatible with drugs, excipients, co-solvents and skin penetration enhancers is disclosed which includes a cohesive strengthening agent. The adhesive is useful as a transdermal drug delivery device. A blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2, lines 13+). Note that instant claim 7 recite a molecular weight of about 600,000 to about 1,000,000. Shear values were measured by using a 4.5 lb. rubber roller and allowed to equilibrate for 20 minutes. The specimen is mounted into the jaws of the Instron and pulled at a speed of 0.5 cm/min. and the peak load required to shear and separate the laminate is recorded in kg (page 8, lines 14+, see also table C2), It is the position of the Examiner that since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping. With regard to instant claim 5, Pfister discloses that the liquids are allowed to evaporate in room temperature (see examples A and B), which makes the composition substantially free of water and solvents. Pfister also discloses a pressure sensitive adhesive sandwiched between a backing substrate and a release liner (figure 1), and the delivery device is a matrix-type for a bioactive agent or drug in place within a transdermal patch (see figure 2) having the sufficient tack and shear to remain in place

under conditions of use. Tack, peel, and adhesion values are disclosed (page 7, lines 40+). The methods recited in instant claims 17, and 21 is a conventional method comprising mixing polymer(s), drug(s) and solvent(s), forming a matrix then evaporating the solvent. The method is disclosed in example A, and B.

Because the same compounds have same properties, the recitation of "pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit" is an inherent property to the same compounds of the preparation disclosed by Pfister.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al. EP 0524776 in view of Lee et al US 5284660 and further in view of Horstman et al. US 5230898 (Horstman).

Pfister was relied upon for the reasons set forth hereinabove.

Pfister did not disclose the percentage of the drug used in the invention.

Lee teaches a device suitable for transdermal administration has a backing layer, which is not permeable to the agent delivered (col. 4, lines 10+). The delivered drug can be nicotine (col. 7, line 23); the amount of the drug is 40% of the dry composition (example 1, claims 13, 14, 19, and 20). In addition, it is noted that adjusting a specific transdermal dose of a drug is within a skilled artisan according to the condition it will be used for among many other factors while choosing between the different kinds of polymers recognized in the art to build a release-profile is also within the skills of an artisan unless documented by unexpected data results. Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the knowledge of Pfister with the dosage disclosed by Lee, the motive would be the disclosure of Pfister that his invention provide a transdermal pressure sensitive with having the sufficient tack and shear to remain in place under conditions of use.

None of the references teach amphetamine in the transdermal delivery system.

Horstman teaches a transdermal therapeutic system exhibiting an increased active substance flow and process for the production, the system includes a layer serving as drug-reservoir, pressure-sensitive adhesive (col. 1, line 24). This layer comprises amphetamine (claim 6).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include amphetamine in the pressure-sensitive adhesive transdermal delivery system since the two inventions are in the same field and because the prior art

suggested and achieved acceptable results in comprising amphetamine in the said system. The skilled artisan would have expectations of success since amphetamine has previously been included in transdermal delivery systems successfully.

Note that instant claims 24-26 were properly rejected in the final office action, however, the claims were missed in the head of the rejection due to a typographical error (final office action pages 4, 5, and 7 for nicotine, pages 4 and 6 for free-base or free-acid form and page 8 for amphetamine).

(10) Response to Argument

Claim Rejections - 35 USC § 112

Applicant argues that: “processing temperatures” are the temperatures at which the transdermal compositions are processed and that this is sufficient to render the claim clear. Further "Equal to or greater than the normal boiling points of the at least one low molecule weight drug " is clear and definite as written.

To respond: definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent and to provide a clear measure of what applicants regard as their invention. It is noted that the scope of the claims cannot be determined since Applicant compares to properties of materials that are not recited in the claims such as the active agent and/or the adhesive polymers. In addition using “below processing temperature” or “equal to or greater than the boiling points of the at least one low molecular weight drug”. This adds to indefiniteness of the claim since Applicant compares to an unknown values that are related to properties of an unknown material. Accordingly, the claims are not clear of what it include or exclude.

Claim Rejections - 35 USC § 102

WO 93/00058 to Miranda et al.:

Applicant argues that: Miranda fails to disclose a polymer blend comprising a "high shear resistant acrylic-based pressure sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° F as claimed. The Office Action does not explain with sufficient rationale how Miranda inherently provides this teaching, as required for a rejection based on inherency.

To respond: A compound and its properties are not separable, the prior art clearly used the same polymers in the same invention (polyacrylates in transdermal composition). Miranda describes an acrylic polymer which is in a preferred embodiment, the multiple polymer adhesive system that comprises a blend of an acrylic shear-resistant pressure-sensitive adhesive and a silicone pressure-sensitive adhesive (page 5). The prior art clearly administers same ingredient (acrylic shear-resistant pressure-sensitive adhesive) in the same delivery form (transdermal) to same patients (in need for transdermal drug delivery systems). It is not necessarily that the prior art recognizes each and every advantage that a compound can accrue from the use of the particular ingredient. Prior art administers to the same patient population therefore there's no invention in the recognition of these properties.

Applicant argues that: Miranda et al. does not anticipate the claimed invention because it does not disclose a transdermal drug delivery system comprising a blend of a) polymers; b) one or more drugs at least one of which is a low molecular weight. The office action fails to identify any particular polymer described as "high shear resistant acrylic based pressure-sensitive adhesive polymer".

To respond: Miranda used the same drug recited in the instant claims "nicotine", and the same blend of polymers recited in the instant claims "polyacrylate and polysiloxane" to achieve the same result of having a transdermal drug delivery system. Further, instant specification discloses the se of any polyacrylate (pages 13-14) while Miranda teaches almost any

polyacrylate (pages 15 and 18). The reference does not have to describe the ingredients of the composition in the same words which Applicant uses.

Applicant argues that: Miranda application discloses compositions which include acrylic-based polymers such as Duro-Tak 80-1194, Duro-Tak 80-11196, and Duro-Tak 80-1197. However, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21, or greater than or equal to 50 hours at 8 pounds per square inch and 720 Fahrenheit as set forth in claims 2-18. Thus, the '058 application does not anticipate claims 2-21.

To respond: Applicant is contradicting his own disclosures. **Parent patent US 6,316,022 to Mantelle et al.** (same inventive entity), discloses an invention, wherein a preferred embodiment, the high shear resistant polymer has a shear resistance which is gtoreq 50 hours at 4 pounds per square inch (psi) and 72º F, more preferably gtoreq.100 hours at 4 psi and 72º F, even more preferably gtoreq.100 hours at 8 psi and 72º F (col. 3, lines 52+). The polymers used in the 6,316,022 invention include the polyacrylate adhesives sold under the trademarks Duro-Tak 80-1194, 80-1196, 80-1197, 87-2287, 87-2516 and 87-2852 by National Starch and Chemical Corporation, Bridgewater, New Jersey. Other suitable acrylic adhesives are those sold under the trademarks Gelva-Multipolymer Solution GMS 737, 788, 1151 and 1430 (Monsanto; St. Louis, Mo.) (col. 8, lines 31+). Accordingly, Applicant used the same trademarks of polymers used by Miranda in his patent 6,316,022 and disclosed that the shear resistance of these polymers is .gtoreq. 50 hours at 4 pounds per square inch (psi) and 72º Fahrenheit, more preferably. Gtoreq.100 hours at 4 psi and 72º F, even more preferably .gtoreq.100 hours at 8 psi and 72º F. patent 6316022, used Duro-Tak 87-2194 in all examples (examples 1-37) to ensure obtaining the properties recited in the instant claims. Instant disclosure used the same polymer

in all examples (examples 1-37). (See parent patent 6316022, to Mantelle et al. as evidence submitted to support the position of the Examiner).

EP 0524776 to Pfister et al.:

Applicant argues that: Pfister does not anticipate the instant claims comprising one or more polymers of high shear resistant acrylic-based pressure-sensitive adhesive polymer and a therapeutically effective amount of one or more drugs of a low molecular weight that is liquid at room temperatures as set forth in instant claim 1.

To respond: Pfister teaches a blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance (page 5, lines 13+), and nicotine-based drug, and co-solvent excipients (page 2, lines 13+)

Applicant argues that: EP '776 teaches the use of a "carbomer" in its silicone-based pressure sensitive adhesive, the "carbomer" is not a "high shear resistant acrylic-based pressure sensitive adhesive polymer," as recited in claim 1. Instead, the carbomer is used as a "cohesive strengthening agent" (e.g., a filler) and is dispersed in the silicone pressure-sensitive adhesive to increase cohesive strength. See EP '776, page 5, lines 29-30.

To respond: the carbomer used is a polyacrylic acid, which is an acrylic-based polymer. In addition, Pfister teaches that the desirable values of shear range between 15-25 kg. As shown in Table C2, values ranged from 18.0 (+/- 0.8) to 23.9 (+/- 0.0) kg which is within the range of the instant claims. Finally, Pfister comprised an acrylic-based polymer to achieve the same goal desired by Applicant; the resulting shear resistance is inherent.

Applicant argues that: The Office Action further argues that "Table C2" allegedly provides evidence of inherency of the recited shear resistance because the values in Table C2 are allegedly "within the range of the instant claims." However, this is a misrepresentation of Table C2. Page 14 of Pfister describes the shear of the entire adhesive composition.

To respond: even if the shear-resistance includes the whole adhesive composition, it is the position of the Examiner that since Pfister discloses acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+) this amount is overlapping with instant claim 7, then the shear-resistance is expected to overlap as well.

Claim Rejections - 35 USC § 103

Applicant argues that: as shown in the arguments Pfister does not teach or suggest the invention recited in the independent claims, and thus neither Lee nor Horstman remedy this deficiency, the combination of Pfister, Lee and Horstman does not render the claimed invention obvious.

To respond: As responded hereinabove, Pfister anticipates the instant claims and consequently makes obvious all the claims combined with Lee and Horstman.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Nabila G Ebrahim/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

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